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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/628,004  | 07/25/2003  | Abraham Pinter       | ABX-PHRI CON        | 3975             |
| 1473  | 7590        | 12/14/2006           | EXAMINER            |                  |
| FISH & NEAVE IP GROUP<br>ROPES & GRAY LLP<br>1251 AVENUE OF THE AMERICAS FL C3<br>NEW YORK, NY 10020-1105 |             |                      | HILL, MYRON G       |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1648                |                  |

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/628,004             | PINTER ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Myron G. Hill          | 1648                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 25 September 2006.  
2a)  This action is **FINAL**.                            2b)  This action is non-final.  
3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) See Continuation Sheet is/are pending in the application.  
4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1,10-16,22 and 23 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/8/04.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .  
5)  Notice of Informal Patent Application  
6)  Other: \_\_\_\_ .

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on 9/25/2006 is acknowledged. The traversal is on the ground(s) that this should be a species election. This is found persuasive. When a generic claim is found allowable such species as properly dependent on the allowed claim will be rejoined.

The requirement is still deemed proper and is therefore made FINAL.

Claims 24, 25, 27, 28, 31-33, 35-41, 43-46, 52, 61-68, 71, 72, 78, 94, 109-112, 114-116, 118-123, 133 and 135-138 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 53, 55, 69, 70, 85, 88, 90, 91, 97, 102, 104, 107, and 139 are generic and will be examined with the elected invention.

This action is on claims 1, 10-16, 22, 23, 53, 55, 69, 70, 85, 88, 90, 91, 97, 102, 104, 107, and 139.

***Information Disclosure Statement***

A signed and initialed copy of the IDS paper filed 8 March 2004 is enclosed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 20, 22, and 23 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for the said claims. The specification does not provide a repeatable method for obtaining the specific antibody ATCC PTA-3002. Deposit of the antibody would satisfy the enablement requirements of 35 U.S.C. 112. Applicant's deposit statement in specification does not indicate the extent of public availability.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10-14, 16, 53, 55, 69, 70, 85, 88, 90, 91, 97, 102, 104, 107, and 139 are rejected under 35 U.S.C. 102(a) as being anticipated by Burton *et al.*

Burton *et al.* teach neutralizing antibodies to strains of HIV that bind at the CD4 binding site (page 1024 column 3 first full paragraph).

The antibodies are disclosed are monoclonal, recombinantly made antibodies that neutralize various isolates (Table 1), and compete with other antibodies (page 1026 column 2 middle).

Where, as here, the Patent Office lacks the facilities to perform comparisons between the claimed material and prior art materials that reasonably appear to meet the claim limitations, the burden is properly shifted to applicant to distinguish the claimed product from the prior art product. See *In re Best, Bolton, and Shaw*, 195 USPQ 430 (CCPA 1977); *Ex Parte Gray*, 10 USPQ2nd 1922 (BPAI 1989).

Thus, Burton *et al.* anticipates the claimed invention.

Claims 1, 10-14, 16, 53, 55, 69, 70, 85, 88, 90, 91, 97, 102, 104, 107, and 139 are rejected under 35 U.S.C. 102(a) as being anticipated by Pinter *et al.*

Pinter *et al.* teach neutralizing antibodies to strains of HIV that bind an epitope of the V1/V2 domain (abstract). They teach neutralization of various isolates (Figure 1 and Table 3).

Where, as here, the Patent Office lacks the facilities to perform comparisons

between the claimed material and prior art materials that reasonably appear to meet the claim limitations, the burden is properly shifted to applicant to distinguish the claimed product from the prior art product. See *In re Best, Bolton, and Shaw*, 195 USPQ 430 (CCPA 1977); *Ex Parte Gray*, 10 USPQ2nd 1922 (BPAI 1989).

Thus, Pinter *et al.* anticipates the claimed invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 10-16, 22, 23, 53, 55, 69, 70, 85, 88, 90, 91, 97, 102, 104, 107, and 139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kayman *et al.* (US5643756).

Kayman *et al.* teach that antibodies to the V2 loop are neutralizing have a construct that displays the V1/V2 loop in a conformational correct way to make antibodies, and that any sequence of a known strain can be used in this construct (column 3).

One of ordinary skill in the art at the time of invention would have been able to make neutralizing antibodies to V1/V2 loops of gp120 of any known strain. Recombinant methods and antibody manipulations (detectable labels etc.) are well known in the art.

Because the expression structure used by Kayman *et al.* include the V1 loop, the V1 portion is required to make the antibody. The construct was used to detect neutralizing antibodies (examples).

Thus it would have been *prima facie* obvious to make neutralizing antibody or a fragment thereof that recognizes an epitope on the V1/V2 domain of HIV-1 gp120 with the expectation of success because making and screening antibodies from expressed peptides is well known in the art.

#### ***Double Patenting***

Claims 1, 10-13, 15, 16, 22, 23, 53, 55, 69, 70, 85, 88, 90, 91, 97, 102, 104, 107, and 139 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-20 of U.S. Patent No. 6815201. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to antibodies that bind the V1/V2 loop.

#### ***Conclusion***

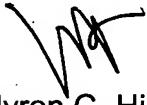
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Myron G. Hill  
Patent Examiner  
7 December 2006



BRUCE R. CAMPELL, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Continuation of Disposition of Claims: Claims pending in the application are 1,10-16,19,20,22-25,27,28,31-33,35-41,43-46,52,53,55,61-72,74,78,85,88,90,91,94,97,102,104,107,109-112,114-116,118-123,133 and 135-139.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 19,20,24, 25,27,28,31-33,35-41,43-46,52,53,55,61-72,74,78,85,88,90,91,94,97,102,104,107,109-112,114-116,118-123,133 and 135-139.